

## RESPONSE TO HEALTH OFFICER INQUIRY: REASONS FOR VACCINE SHORTAGES

### Reasons for the Shortages Overall

The nation has been experiencing shortages of several of the routine childhood vaccines since mid 2000. Although there are some differences in the underlying causes of shortages among the various vaccines, there are several over-arching factors that are applicable to the vaccine shortages in general. They include:

1. Decreased or limited numbers of manufacturers producing and supplying vaccines.
2. Removal of thimerosal containing vaccines from the supply.
3. Production changes due to the removal of the preservative thimerosal in some childhood vaccines.
4. Temporary or periodic discontinuation of production to allow for production practice changes or upgrades, due to external or internal audit of production practices.
5. Pricing differentiation between the public sector and the private sector that leads to manufacturers' selecting in some cases to provide a greater amount of the shortage vaccines to the private sector than to the public sector.

### Reasons for the Shortages by Vaccine

DTaP and Tetanus Related Vaccines -- The nation has been experiencing shortages of several vaccines since mid-2000. The earliest shortage was in Tetanus and tetanus related vaccines, such as DTaP, Td, T, DT, and DTaP/HIB, for which tetanus is the limiting factor. This shortage stemmed from several key factors:

1. In late 1999, public concern over the use of the preservative thimerosal in childhood vaccines lead to the removal of thimerosal containing vaccines from the market, and revamping the manufacturing process for those vaccines, effecting the production of DTaP, DTaP/HIB, and other vaccines.
2. The number of manufacturers of tetanus and tetanus related vaccines decreasing from 4 to 1 over a period of about 3 years. In 2000, a manufacturer that had previously produced 32 percent of the national product need for diphtheria and tetanus products discontinued production of Td, leaving a single national producer of Td. Shifting shares of the market, changes in production activities, and the length of time needed to grow the tetanus virus have all limited the availability of tetanus and tetanus related vaccines.
3. There also has been some discrepancy in the availability of DTaP vaccines for the public sector, which purchases the vaccine at a lower cost, versus the private sector.

All of these factors have contributed to the current shortage problems. As we begin to see the resolution of the Td shortage, the shortages for other tetanus containing vaccines, such as DTaP, will begin to resolve as well. Just recently, there has been some improvement in the Td supply. Although the restrictions for Td vaccination continue, the vaccine will be made available to the private sector in the summer of 2002. The DTaP shortage is anticipated to be resolved by the end of 2002.

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PCV-7 (pneumococcal conjugate vaccine 7 valiant) Vaccines -- Nationally, the shortage of pneumococcal conjugate vaccine has been felt equally in both the public and private sectors. Key factors contributing to the availability of PCV-7 include:

1. A single manufacturer producing the vaccine.
2. Unanticipated rapid implementation in the public sector, and high demand for the vaccine, resulting in a demand that exceeded manufacturing projections and supply.
3. Manufacturer experiencing need for re-vamping some manufacturing practices due to audits by the Food and Drug Administration.

The manufacturer indicates that production for 2002 will soon meet the demand though inventory build-up may not be sufficient to return to the “routine schedule” before fall 2002.

Varicella Vaccine -- The Varicella supply was primarily affected by delays caused by updating production practices. This is also a vaccine with a single licensed supplier in the United States.

1. Both public and private providers in all states have experienced critical shortages.
2. States that have included Varicella vaccination as part of their requirements for childcare and/or school attendance are advised to consider options for allowing conditional entry until the vaccine is available to update the child’s immunizations.
3. ACIP has recommended that routine Varicella vaccinations be delayed from 12-18 months of age to 18-24 months of age (see MMWR, March 8, 2002).

Providers may be able to return to recommended schedule by early summer 2002.

Measles, Mumps, Rubella (MMR) Vaccine -- The MMR supply was primarily affected by delays caused by updating production practices. This is also a vaccine with a single licensed supplier in the United States.

1. The MMR supply is rapidly improving nationally; in Washington State, we have been virtually unaffected by this short-term shortage.
2. Nationally, ACIP has recommended that providers suspend the second dose of MMR if their supply is insufficient (MMWR, March 8, 2002).